WHAT IS CLAIMED IS:

1. A method for detecting autoantibodies to an approximately 64kD pancreatic β-cell autoantigen in sera, said method comprising exposing a serum sample to purified ligand for the autoantibodies and detecting specific interaction between the purified ligand and the autoantibodies.

2. A method as in claim 1, wherein the purified ligand is glutamic acid decarboxylase or a fragment thereof.

3. A method as in claim 2, wherein the glutamic acid decarboxylase is isolated from a natural source.

4. A method as in claim 2, wherein the glutamic acid decarboxylase is synthetic.

5. A method as in claim 2, wherein the glutamic acid decarboxylase is lower molecular weight CNS GAD.

6. A method as in claim 2, wherein the glutamic acid decarboxylase is pancreatic GAD.

7. A method as in claim 1, wherein the serum sample is combined with soluble, labelled autoantibodies so that labelled and unlabelled autoantibodies compete to form complexes with the purified ligand, whereby the amount of label bound in such complexes is inversely proportional to the concentration of autoantibodies initially present in the serum sample.

8. A method as in claim 7, wherein the autoantibodies are labelled with an enzyme and binding of ligand to the autoantibodies inhibits enzyme activity.

9. A method as in claim 7, wherein the purified ligand is bound to a solid phase and the method further comprises removing the solid phase from the serum sample in order to separate labelled complexes from unbound, labelled autoantibodies.

10. A method as in claim 9, wherein the label present on the solid phase is measured.

11. A method as in claim 9, wherein the label remaining in the serum sample is measured.

12. A method as in claim 1, wherein the purified ligand is bound to a solid phase and the method further comprises separating the solid phase to remove substantially all autoantibodies present in the sample and measuring the amount of autoantibodies removed, whereby the amount is directly proportional to the concentration of autoantibodies present in the sample.

13. A method as in claim 12, wherein the amount of autoantibodies is measured by exposing the solid phase to labelled reagent specific for the autoantibodies and determining the amount of bound labelled reagent.

14. A method as in claim 1, wherein the purified ligand possesses glutamic acid decarboxylase activity and the interaction between the ligand and the autoantibodies is detected based on loss of enzyme activity.

15. A method for diagnosing or monitoring insulin dependent diabetes mellitus and related conditions in a patient, said method comprising:

obtaining a serum sample from the patient;

exposing the serum sample to purified glutamic acid decarboxylase or a fragment thereof; and

detecting interaction between the glutamic acid decarboxylase and autoantibodies which may be present in the serum sample, wherein such interaction is diagnostic of insulin dependent diabetes mellitus.

16. A method as in claim 15, wherein the glutamic acid decarboxylase is isolated from a natural source.

17. A method as in claim 15, wherein the glutamic acid decarboxylase is synthetic.

18. A method as in claim 15, wherein the glutamic acid decarboxylase is lower molecular weight CNS GAD.

19. A method as in claim 15, wherein the glutamic acid decarboxylase is pancreatic GAD.

20. A method as in claim 15, wherein the serum sample is combined with soluble, labelled autoantibodies so that labelled and unlabelled autoantibodies compete to form complexes by binding to the purified glutamic acid decarboxylase, whereby the amount of label bound in such complexes is inversely proportional to the concentration of autoantibodies initially present in the serum sample.

21. A method as in claim 15, wherein the autoantibodies are labelled with an enzyme and binding of ligand to the autoantibodies inhibits enzyme activity.

22. A method as in claim 20, wherein the purified glutamic acid decarboxylase is bound to a solid phase and the method further comprises removing the solid phase from the serum sample in order to separate labelled complexes from unbound, labelled autoantibodies.

23. A method as in claim 22, wherein the label present on the solid phase is measured.

24. A method as in claim 22, wherein the label remaining in the serum sample is measured.

25. A method as in claim 15, wherein the purified glutamic acid decarboxylase is bound to a solid phase and the method further comprises separating the solid phase to remove substantially all autoantibodies present in the sample and measuring the amount of autoantibodies removed, whereby the amount is directly proportional to the concentration of autoantibodies present in the sample.

26. A method as in claim 25, wherein the amount of autoantibodies is measured by exposing the solid phase to labelled reagent specific for the autoantibodies and determining the amount of bound labelled reagent.

27. A method as in claim 15, wherein the purified glutamic acid decarboxylase possesses native enzyme activity and the interaction is detected based on loss of enzyme activity.

28. A method for diagnosing insulin dependent diabetes mellitus and related conditions in a patient, said method comprising:

obtaining a serum sample from the patient;

assaying the sample to determine the presence of autoantibodies against glutamic acid decarboxylase, whereby presence of such antibodies is diagnostic of insulin dependent diabetes mellitus.

29. A method as in claim 28, wherein the assay is a radioimmunoassay employing radiolabelled glutamic acid decarboxylase bound to a solid phase.

30. A method as in claim 28, wherein the assay is an enzyme linked immunoadsorbent assay employing enzyme-labelled glutamic acid autoantibodies and glutamic acid decarboxylase bound to a solid phase.

31. A method for inhibiting the development of insulin dependent diabetes mellitus, said method comprising administering to a patient a preselected dosage of glutamic acid decarboxylase or a fragment thereof.

32. A method as in claim 31, wherein the glutamic acid decarboxylase or fragment thereof is coupled to an immunoglobulin or lymphoid cell from the patient being tested.

33. A method as in claim 32, wherein the glutamic acid decarboxylase or fragment thereof has been modified to decrease binding to an associated T-cell receptor while maintaining binding to the MHC, whereby the cellular immune response is inhibited.

34. A method as in claim 31, wherein the dosage of glutamic acid decarboxylase is selected to induce tolerance in the patient to the 64kD autoantigen associated with insulin dependent diabetes.

35. A composition comprising glutamic acid decarboxylase or a fragment thereof in a pharmaceutically acceptable carrier.

36. A composition as in claim 35, wherein the glutamic acid decarboxylase or fragment thereof is coupled to an immunoglobulin or lymphoid cell.

37. A composition as in claim 35, wherein the glutamic acid decarboxylase or fragment thereof has been modified to decrease binding to an associated T-cell receptor while maintaining binding to the MHC.

38. A method for inducing tolerance to the 64 k autoantigen in diabetic or prediabetic individuals, said method comprising:

exposing peripheral blood cells from the individual to GAD or equivalent ligand *in vitro* to stimulate T-helper cells; and

administering the stimulated T-helper cells or portions thereof to the individual.

39. A method as in claim 38, wherein the T-cell receptor or a portion thereof is administered to the individual.

40. A method as in claim 38, wherein the T-helper cells have been attenuated.

41. T-helper cells which are stimulated by exposure to GAD or equivalent ligand.

42. T-cell receptor peptides from the T-helper cells of claim 41.

43. A method for diagnosing or monitoring insulin dependent diabetes mellitus and related conditions in a patient, said method comprising:

obtaining a serum sample from the patient;

detecting in the sample the presence of autoantibodies to lower molecular weight glutamic acid decarboxylase (GAD); and

detecting in the sample the presence of autoantibodies to higher molecular weight glutamic acid decarboxylase (GAD), wherein the presence of autoantibodies to at least one of the molecular weight forms of GAD indicates the onset or persistance of insulin dependent diabetes mellitus.

44. A method as in claim 43, wherein the autoantibodies to each molecular weight form of GAD are detected separately so that the presence of each form is known.

45. A method as in claim 44, wherein the presence of autoantibodies to each molecular weight form of GAD is separately determined by reaction with recombinantly produced GAD which is free from the ot her molecular weight form.

46. A method as in claim 43, wherein the autoantibodies to each molecular weight form of GAD are detected simultaneously so that the presence of neither form is individually determined.

47. A method as in claim 46, wherein the presence of the autoantibodies is determined by reaction with a mixture of both molecular weight forms of GAD.

48. A method as in claim 47, wherein the mixture is isolated from a source of native CNS GAD.